



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,322	03/19/2004	Kevin A. Wanasek	P-11455.00	7316
27581	7590	03/27/2006		
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924				
			EXAMINER MALAMUD, DEBORAH LESLIE	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/804,322	Applicant(s) WANASEK, KEVIN A.	
	Examiner Deborah Malamud	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgement is made of the amendments received 23 January 2006.

Specification

2. In view of the corrections made to the specification, the examiner withdraws the objection to the specification.

Claim Objections

3. In view of the amendments to the claims, the examiner withdraws the objections to claims 15 and 23, due to minor informalities.

Claim Rejections - 35 USC § 102

4. Applicant's arguments, filed 23 January 2006, with respect to the rejections of claims 1,4,7 and 8 under Imran et al (U.S. 4,614,192); claims 1, 4, 9 and 17 under Stemple (4,566,457); and claim 24 under Altman et al (U.S. 4,726,379) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of Keimel (5,163,427).

5. Claims 1, 5 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Keimel (U.S. 5,163,427). Keimel discloses (column 1, lines 65-68; column 2, lines 1-22) "a pulse generator for use in conjunction with an implantable cardioverter/defibrillator" whose output stage is "provided with two separate capacitor banks, which are sequentially discharged during sequential pulse defibrillation and simultaneously discharged during single or simultaneous pulse defibrillation." A first control signal "triggers discharge of the first capacitor bank between first and second electrodes. A

second control signal triggers discharge of both capacitor banks between a third electrode and the first electrode. Simply by modifying the number and time order of the control signals, it is possible to select between the three defibrillation pulse regimes."

The examiner considers this to teach an energy storage device, a plurality of electrodes electrically coupled to the energy storage device, and control circuitry, coupled to the energy storage device and the plurality of electrodes, generating the pulse waveform from the stored energy and delivering the pulse waveform to the target site via the plurality of electrodes. The pulse waveform corresponds to multiple signals delivered simultaneously to multiple pathways between the plurality of electrodes.

Regarding claim 5, Keimel discloses (column 3, lines 25-35) "cardiac pacing pulses are delivered between helical electrode (34) and elongated electrode (28). Electrodes 28 and 34 are also employed to sense electrical signals indicative of ventricular contractions. As illustrated, it is anticipated that the right ventricular electrode (28) will serve as the common electrode during sequential and simultaneous pulse multiple electrode defibrillation regimens. For example, during a simultaneous pulse defibrillation regimen, pulses would simultaneously be delivered between electrode (28) and electrode (30) and between electrode (28) and electrode (32)." The examiner considers this to teach a Delta configuration of electrodes about the target site.

Regarding claims 7-8, Keimel discloses (column 3, lines 1-3) "lead (14) is coupled to a subcutaneous electrode (30), which is intended to be mounted

subcutaneously in the region of the left chest." The examiner considers this to be a non-intracardiac electrode.

Claim Rejections - 35 USC § 103

6. Applicant's arguments, filed 23 January 2006, with respect to the rejections of claims 2 and 3 under Imran et al (U.S. 4,614,192) in view of Belt (U.S. 4,436,093); claims 6 under Imran in view of Kuck et al (U.S. 5,921,923); claim 10 under Imran in view of Belt in further view of Kuck; claims 11, 13 and 15-16 under Imran in view of Stemple (4,566,457); claims 12 and 14 under Stemple in view of Kuck; claims 18-19 under Stemple in view of Belt; and claims 20 and 22-23 under Stemple in view of Imran have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Keimel (5,163,427).

7. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keimel (U.S. 5,163,427) in view of Belt (U.S. 4,436,093). Keimel fails to teach a predetermined phase shift for the multiple signals. Belt however discloses (column 9, lines 44-49) "a sampling rate of four times the power line frequency is provided by the four sampling channels, each having a 90 degree phase relationship to each other. It will be appreciated that a greater number of channels may be employed where greater resolution is required." Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keimel's ICD with Belt's signal phase shift in order to achieve greater resolution of the signal provided by the ICD.

Regarding claim 3, Keimel in view of Belt discloses the claimed invention but does not disclose expressly the value of the predetermined phase shift of the signal. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the phase shift as taught by Belt, with the value of 120 degrees, because the applicant has not disclosed the phase shift value provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the phase shift of 90 degrees as taught by Belt, because the signal of Belt's system is adequate for resolution, and nothing prevents Belt's phase shift from being used in the applicant's system. Therefore, it would have been an obvious matter of design choice to modify the defibrillator of Keimel in view of Belt to obtain the invention as specified in the claim.

8. Claims 4, 9, 11, 13, 15-17, 20 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keimel (U.S. 5,163,427) in view of Stemple (U.S. 4,566,457). Regarding claims 4, 9 and 16, Keimel discloses the claimed invention except for a smoothing element positioned electrically in series with the energy storage device. Stemple however discloses (column 4, lines 18-21) "the safety circuit may include an inductor, for example an air coil, which serves for pulse shaping during the defibrillation shock procedure." See Fig. 6. Keimel and Stemple both disclose defibrillator circuits for treating the heart. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keimel's multiple simultaneous signal with

Art Unit: 3766

Stemple's smoothing element in order to better control the output signal of the electrical therapy.

Regarding claim 17, Keimel discloses the claimed invention except for controlling switching elements associated with each of the plurality of electrodes in a predetermined pattern. Stemple however discloses (column 6, lines 3-10) a circuit that includes a "discharging line, which is also connected to the capacitors C_1 through C_n [energy storage capacitors] by way of respective switches SE_1 through SE_n connected in series with respective ones of the capacitors. It will be seen therefore that discharge of the capacitor array is effected by way of the discharge line when the switches SL_1 through SL_n are in an open condition and the switches SE_1 through SE_n connected in series with the capacitors are serially closed at given intervals of time. In this case also the serial combination of the individual capacitor voltages, with simultaneous discharge by way of the electrodes (3) and (4), provides for the formation of an individually definable discharge curve." Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keimel's multiple simultaneous pulse therapy with Stemple's switching elements in order to select different therapy regimes on a case-by-case basis.

Regarding claims 11 and 13, Stemple discloses the claimed invention except for a third pair of switching elements, a third electrode and multiple smoothing elements. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stemple's defibrillation circuit with a third pair of switching elements, a third electrode and a plurality of smoothing elements, since it has been held that mere

Art Unit: 3766

duplication of the essential working parts of a device involves only routine skill in the art.

St. Regis Paper Co. v. Bemis Co., 193 USPQ 8. See MPEP § 2144.04.

Regarding claim 15, Stemple discloses (column 6, lines 3-10) a circuit that includes a “discharging line, which is also connected to the capacitors C_1 through C_n [energy storage capacitors] by way of respective switches SE_1 through SE_n connected in series with respective ones of the capacitors. It will be seen therefore that discharge of the capacitor array is effected by way of the discharge line when the switches SL_1 through SL_n are in an open condition and the switches SE_1 through SE_n connected in series with the capacitors are serially closed at given intervals of time.” The examiner considers this to be a first energy storage element associated with a first switching element and a second energy storage element associated with the second switching element.

Regarding claim 20, Keimel discloses (column 3, lines 25-35) “cardiac pacing pulses are delivered between helical electrode (34) and elongated electrode (28). Electrodes 28 and 34 are also employed to sense electrical signals indicative of ventricular contractions. As illustrated, it is anticipated that the right ventricular electrode (28) will serve as the common electrode during sequential and simultaneous pulse multiple electrode defibrillation regimens. For example, during a simultaneous pulse defibrillation regimen, pulses would simultaneously be delivered between electrode (28) and electrode (30) and between electrode (28) and electrode (32).” The examiner considers this to teach a Delta configuration of electrodes about the target site.

Regarding claims 22-23, Keimel discloses (column 3, lines 1-3) "lead (14) is coupled to a subcutaneous electrode (30), which is intended to be mounted subcutaneously in the region of the left chest." The examiner considers this to be a non-intracardiac electrode.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keimel (U.S. 5,163,427) in view of Kuck et al (U.S. 5,921,923). Keimel discloses the claimed invention except for a fourth electrode that can form a Wye configuration about the target site. Kuck however discloses (column 6, lines 31-36) "the first and second electrodes can be electrically connected (through switch element), forming a unified tip electrode. A conventional fourth bipolar signal can be obtained between the unified tip electrode and the third electrode in the second plane along the body axis." Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keimel's defibrillator with Kuck's electrode array in order to create additional signals for diagnostic function within the defibrillator.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keimel (U.S. 5,163,427) in view of Belt (U.S. 4,436,093) in further view of Kuck et al (U.S. 5,921,923). Keimel in view of Belt fails to teach a bipolar signal for each of the electrodes. Kuck however discloses (column 3, lines 3-5) a multiple electrode array comprising at least three, mutually spaced apart electrode elements, wherein the spaced apart elements are also "electrically isolated one from the other, so that bipolar signal readings can be obtained between selected electrode pairs." The electrode array can (column 3, lines 20-22) "continuously record multiple electrical events at different

relative orientations, all within a localized area.” Keimel, Belt and Kuck all teach cardiac pacers with various stimulation regimes. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keimel’s defibrillator with Belt’s predetermined signal and Kuck’s bipolar signal in order to add a diagnostic function to the defibrillator, wherein the diagnostic function has a great resolution for more precise interpretation of the signal.

11. Claims 12, 14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keimel (U.S. 5,163,427) in view of Stemple (U.S. 4,566,457) in further view of Kuck et al (U.S. 5,921,923). Keimel in view of Stemple fails to teach a bipolar signal for each of the electrodes. Kuck however discloses (column 3, lines 3-5) a multiple electrode array comprising at least three, mutually spaced apart electrode elements, wherein the spaced apart elements are also “electrically isolated one from the other, so that bipolar signal readings can be obtained between selected electrode pairs.” The electrode array can (column 3, lines 20-22) “continuously record multiple electrical events at different relative orientations, all within a localized area.” Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keimel’s multiple simultaneous pulse therapy with Stemple’s defibrillator circuit and with Kuck’s bipolar signal in order to add a diagnostic function to the defibrillator.

Regarding claim 14, Kuck discloses (column 6, lines 31-36) “the first and second electrodes can be electrically connected (through switch element), forming a unified tip electrode. A conventional fourth bipolar signal can be obtained between the unified tip electrode and the third electrode in the second plane along the body axis.” The

examiner considers this to be an output switching element coupled to the control circuitry that controls a state of the output switching element to alternate between a Delta configuration and a Wye configuration.

Regarding claim 21, Kuck discloses (column 6, lines 31-36) "the first and second electrodes can be electrically connected (through switch element), forming a unified tip electrode. A conventional fourth bipolar signal can be obtained between the unified tip electrode and the third electrode in the second plane along the body axis." The examiner considers this fourth electrode to form a Wye configuration with the other electrodes.

12. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keimel (U.S. 4,163,427) in view of Stemple (U.S. 4,566,457) in further view of Belt (U.S. 4,436,093). Keimel in view of Stemple fails to teach a predetermined phase shift for the multiple signals. Belt however discloses (column 9, lines 44-49) "a sampling rate of four times the power line frequency is provided by the four sampling channels, each having a 90 degree phase relationship to each other. It will be appreciated that a greater number of channels may be employed where greater resolution is required." Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keimel's multiple simultaneous pulse therapy with Stemple's defibrillator circuit and with Belt's signal phase shift in order to achieve greater resolution of the signal provided by the defibrillator.

Regarding claim 19, Stemple in view of Belt discloses the claimed invention but does not disclose expressly the value of the predetermined phase shift of the signal. It

Art Unit: 3766

would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the phase shift as taught by Belt, with the value of 120 degrees, because the applicant has not disclosed the phase shift value provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the phase shift of 90 degrees as taught by Belt, because the signal of Belt's system is adequate for resolution, and nothing prevents Belt's phase shift from being used in the applicant's system. Therefore, it would have been an obvious matter of design choice to modify the defibrillator circuit of Stemple in view of Belt to obtain the invention as specified in the claim.

13. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al (U.S. 4,726,379) in view of Keimel (U.S. 4,163,427). Altman discloses (column 4, lines 40-47) "a cardiac pacer comprising a ventricular channel subsystem and an atrial channel subsystem, each subsystem having: a lead for receiving cardiac signals; a sensing circuit for sensing cardiac signals; a stimulator for supplying cardiac stimulating pulses; and a switched capacitor circuit operable to transmit cardiac signals from the lead of the subsystem to the sensing circuit of the subsystem such that the subsystem provides no return current path for stimulating pulses from the stimulator of the other subsystem." Altman further discloses (column 12, lines 15-16) a programmable microcontroller that "would include memory storage and a programmed microprocessor." Altman teaches the claimed invention except for Keimel's multiple simultaneous pulse signals. Therefore it would have been obvious to one of ordinary


skill in the art at the time of the invention to modify Altman's cardiac pacer microprocessor with Keimel's multiple simultaneous pulse signals in order to deliver a highly directionalized current to the variety of electrodes used for sensing and stimulating.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766


Deborah L. Malamud
Patent Examiner
Art Unit 3766